

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)****Title of
Invention****ACTIVATION OF RECOMBINANT DIPHTHERIA TOXIN FUSION PROTEINS BY SPECIFIC
PROTEASES HIGHLY EXPRESSED ON THE SURFACE OF TUMOR CELLS**

As the below named inventor(s), I/we declare that:

This declaration is directed to:

- ☐ The attached application, or
- ☒ Application No. 10/554,076, filed on October 21, 2005,
- ☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

All statements made herein of my/our own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon:

FULL NAME OF INVENTOR(S)Inventor one: Stephen H. LepplaCitizen of: United StatesSignature: Date: 21 MARCH 2007Inventor two: Jennifer AvalloneCitizen of: United States

Signature: _____

Date: _____

☒ Additional inventors or a legal representative are being named on 1 additional form(s) attached hereto.

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention	ACTIVATION OF RECOMBINANT DIPHTHERIA TOXIN FUSION PROTEINS BY SPECIFIC PROTEASES HIGHLY EXPRESSED ON THE SURFACE OF TUMOR CELLS
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- ☒ Application No. 10/554,076, filed on October 21, 2005,
- ☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

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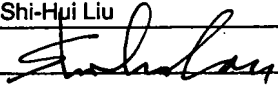
All statements made herein of my/our own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon:

FULL NAME OF INVENTOR(S)	
Inventor one: <u>Stephen H. Leppla</u>	Citizen of: <u>United States</u>
Signature: _____	Date: _____
Inventor two: <u>Jennifer Avallone</u>	Citizen of: <u>United States</u>
Signature: <u>Jennifer Avallone</u>	Date: <u>1/18/07</u>
<input checked="" type="checkbox"/> Additional inventors or a legal representative are being named on <u>1</u> additional form(s) attached hereto.	

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76) –
ADDITIONAL INVENTOR(S)
Supplemental Sheet 1 of 1**

FULL NAME OF INVENTOR(S)	
Inventor three: <u>Thomas Bugge</u>	Citizen of: <u>Denmark</u>
Signature: <u>[Signature]</u>	Date: <u>3/21/07</u>
Inventor four: <u>Shi-Hui Liu</u>	Citizen of: <u>China</u>
Signature: _____	Date: _____
Inventor five: <u>Manuel Osorio</u>	Citizen of: <u>United States</u>
Signature: _____	Date: _____
Inventor six: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor seven: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor eight: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor nine: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor ten: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor eleven: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor twelve: _____	Citizen of: _____
Signature: _____	Date: _____

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76) –
ADDITIONAL INVENTOR(S)
Supplemental Sheet 1 of 1**

FULL NAME OF INVENTOR(S)	
Inventor three: <u>Thomas Bugge</u>	Citizen of: <u>Denmark</u>
Signature: _____	Date: _____
Inventor four: <u>Shi-Hui Liu</u>	Citizen of: <u>China</u>
Signature: <u></u>	Date: <u>21 March, 2007</u>
Inventor five: <u>Manuel Osorio</u>	Citizen of: <u>United States</u>
Signature: _____	Date: _____
Inventor six: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor seven: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor eight: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor nine: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor ten: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor eleven: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor twelve: _____	Citizen of: _____
Signature: _____	Date: _____

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76) –
ADDITIONAL INVENTOR(S)
Supplemental Sheet 1 of 1**

FULL NAME OF INVENTOR(S)	
Inventor three: <u>Thomas Bugge</u>	Citizen of: <u>Denmark</u>
Signature: _____	Date: _____
Inventor four: <u>Shi-Hui Liu</u>	Citizen of: <u>China</u>
Signature: _____	Date: _____
Inventor five: <u>Manuel Osorio</u>	Citizen of: <u>United States</u>
Signature: <u>Manuel Osorio</u>	Date: <u>3/29/07</u>
Inventor six: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor seven: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor eight: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor nine: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor ten: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor eleven: _____	Citizen of: _____
Signature: _____	Date: _____
Inventor twelve: _____	Citizen of: _____
Signature: _____	Date: _____

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT	Application Number	10/554,076
	Filing Date	October 21, 2005
	First Named Inventor	Stephen H. Leppla
	Title	ACTIVATION OF RECOMBINANT DIPHTHERIA TOXIN FUSION PROTEINS BY SPECIFIC PROTEASES HIGHLY EXPRESSED ON THE SURFACE OF TUMOR CELLS
	Art Unit	
	Examiner Name	
	Attorney Docket Number	015280-478100US

I hereby appoint:

☒ Practitioners at Customer Number

45115

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

☒ The above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

OR

<input type="checkbox"/> Firm or Individual Name					
Address					
Address					
City		State		ZIP	
Country					
Telephone		Fax			

I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).
SIGNATURE of Applicant or Assignee of Record

Name	Tasbir S. Kindra		
Signature	Tasbir S. Kindra (Reg. No. 41,115)		
Date	May 10, 2007	Telephone	(301) 435-5559

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

Attorney Docket No. 015280-478100US
DHHS Ref. No. E-331-2002/0-US-03

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Stephen H. Leppla et al.

Application No./Patent No.: 10/554,076

Filed/Issue Date: October 21, 2005

Entitled: ACTIVATION OF RECOMBINANT DIPHTHERIA TOXIN FUSION PROTEINS BY SPECIFIC PROTEASES HIGHLY EXPRESSED ON THE SURFACE OF TUMOR CELLS

The Government of the United States of America as represented by the Secretary of the Department of Health and Human Services.

a government agency

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

(Name of Assignee)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
The extent (by, percentage) of its ownership interest is _____ %

in the patent application/patent identified above by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To : _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To : _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.8]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

May 10, 2007

Date

(301) 435-5559

Telephone number

Jasbir S. Kindra

Typed or printed name

Jasbir S. Kindra (Reg. 41,115)

Signature

Technology Licensing Specialist

Title

ASSIGNMENT

JOINT

WHEREAS, We, Stephen H. Leppla of 9501 Starmont Rd., Bethesda, MD, 20817; Jennifer Avallone of 4 Beehive Lane, Flemington, NJ, 08822; Thomas Bugge of 9802 Bristol Square Lane, Apt. 302, Bethesda, MD, 20814; Shi-Hui Liu of 14516 Settlers Landing Way, Gaithersburg, MD, 20878; and Manuel Osorio of 4710 Bethesda Avenue, #706, Bethesda, MD, 20814 employees of the Department of Health and Human Services at the time the invention was made, have invented (title of invention): ACTIVATION OF RECOMBINANT DIPHTHERIA TOXIN FUSION PROTEINS BY SPECIFIC PROTEASES HIGHLY EXPRESSED ON THE SURFACE OF TUMOR CELLS, for which an application to the Commissioner for Patents for grant of Letters Patents of the United States of America has been executed by the undersigned

☐ on (date(s) Declaration signed):

☒ is identified as U.S. Patent Application:
Serial No. 10/554,076

Filed October 21, 2005; and

WHEREAS, the conditions under which said invention was made are such as to entitle the Government of the United States of America under Paragraph 1(a) of Executive Order 10096, to the entire right, title, and interest herein, both domestic and foreign; and

WHEREAS, the Government of the United States of America is desirous of acquiring all domestic and foreign right, title, and interest in the aforesaid invention described in the aforesaid application for Letters Patent of the United States of America; and

NOW, THEREFORE, to all whom it may concern, be it known that for and in consideration of the premises and other valuable considerations, we the undersigned, have sold, assigned, and transferred and by these presents do sell, assign, and transfer unto The Government of the United States of America as represented by the Secretary of the Department of Health and Human Services (hereinafter THE GOVERNMENT), and his successors, the full and exclusive right, title, and interest throughout the United States of America, its territories and dependencies, and within each and every foreign country in which THE GOVERNMENT elects to file the invention described in the aforesaid application for Letters Patent of the United States of America, and all Letters Patents and Registrations which may be granted on the same in the United States of America and all countries throughout the world, and to claim the priority from the application as provided by the Paris Convention, or of any division, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof.

AND, we hereby authorize and request the Commissioner for Patents to issue said Letters Patent to THE GOVERNMENT as assignee of the entire right, title, and interest in and to the same throughout the United States of America, its territories and dependencies, and within each and every foreign country in which THE GOVERNMENT elects to file, for the sole use for the full term or terms for which said Letters Patent and Registrations may be granted thereon, or of any division, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof which may be granted as fully and entirely as the same would have been held by us, had this assignment not been made;

AND, we hereby warrant that there are no outstanding assignments, grants, liens, encumbrances, or agreements either written, oral, or implied with respect to the aforesaid application for Letters Patent which will impair, diminish, limit, or abridge the interest herein conveyed at the time of the execution of this instrument by us;

AND, we hereby agree to execute any and all applications for Letters Patent in the United States of America and foreign countries, and to furnish and deliver to the Secretary, Department of Health and Human Services, upon request, all data and documents, and to execute any papers which may be necessary for the prosecution of any application or applications of Letters Patent or for THE GOVERNMENT to exercise its rights granted hereunder, including communicating to THE GOVERNMENT, its representatives or agents, any facts relating to said invention, including evidence for interference purposes, or for other proceedings, whenever requested, to testify in any interference or other proceedings, whenever requested, and to execute and deliver on request all lawful papers required to make any of the foregoing provisions effective, and likewise make these provisions binding upon our heirs, legal representatives, administrators and assigns, and we shall assist THE GOVERNMENT in every way as may be requested in protecting said invention, provided that any expense of extending such assistance shall be paid by THE GOVERNMENT.

The undersigned hereby grants THE GOVERNMENT or the law firm of Townsend and Townsend and Crew LLP, the power to insert on this Assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

IN TESTIMONY WHEREOF, Assignors have signed their names on the dates indicated.

Stephen H. Leppa
Stephen H. Leppa

4 Apr 2007
Date

STATE OF Maryland
COUNTY OF Montgomery

UNITED STATES OF AMERICA

On 4th April 2007, before me, CHARLENE D. DIXON **NOTARY PUBLIC** (here insert name and title of the officer), personally appeared Stephen H. Leppa, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, execute the instrument.

WITNESS my hand and official seal.

Signature Charlene D. Dixon

(Seal)

Charlene D. Dixon
NOTARY PUBLIC
Montgomery County, Maryland
My Commission Expires 6/1/2010

Jennifer Avallone
Jennifer Avallone

Date

4/18/07

STATE OF New Jersey)
COUNTY OF Hunterdon)

UNITED STATES OF AMERICA

On 4-18-07, before me, Rhonda L. Sandar (here insert name and title of the officer), personally appeared Jennifer Avallone, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, execute the instrument.

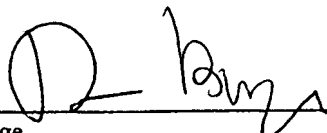
WITNESS my hand and official seal.

Signature

Rhonda L. Sandar
Rhonda L. Sandar

(Seal)

RHONDA L. SANDAR
ID # 2339318
NOTARY PUBLIC OF NEW JERSEY
Commission Expires 1/19/2011



Thomas Bugge

3/21/07

Date

STATE OF Maryland)
)
COUNTY OF Montgomery)

UNITED STATES OF AMERICA

On March 21, 2007, before me, Michael LUM (here insert name and title of the officer), personally appeared Thomas Bugge, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, execute the instrument.

WITNESS my hand and official seal.

Signature 

(Seal)

MICHAEL LUM
NOTARY PUBLIC
MONTGOMERY COUNTY
MARYLAND
MY COMMISSION EXPIRES APRIL 1, 2007

Shi-Hui Liu
Shi-Hui Liu

4/4/07
Date

STATE OF Maryland,
COUNTY OF Montgomery

UNITED STATES OF AMERICA

On 4th April 2007, before me, CHARLENE D. DIXON, Notary Public (here insert name and title of the officer), personally appeared Shi-Hui Liu, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, execute the instrument.

WITNESS my hand and official seal.

Signature Charlene D. Dixon

(Seal)

Charlene D. Dixon
NOTARY PUBLIC
Montgomery County, Maryland
My Commission Expires 6/1/2010

Manuel Osorio
Manuel Osorio

3/29/2007
Date

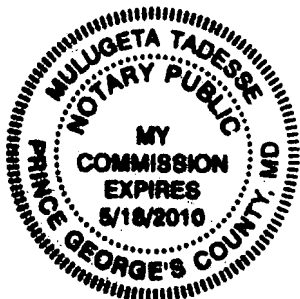
STATE OF Maryland)
COUNTY OF Prince George's)

UNITED STATES OF AMERICA

On 03/29/2007, before me, Mulgeta Tadesse - MSK (here insert name and title of the officer), personally appeared Manuel Osorio, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, execute the instrument.

WITNESS my hand and official seal.

(Seal)



Signature Mulgeta Tadesse

10154111/60979933 v1